MAY 0 8 2002

EXHIBIT 2 K013822

CANÈ S.r.l.
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Contact: Mario Cané, President
November 13, 2001

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: Microjet *Crono* PCA
   Classification Name: MEA
   Common/Usual Name: Ambulatory Infusion Pump

2. **Equivalent legally marketed devices** This product is similar in function to the Cadd-Legacy PCA Model 6300 Ambulatory Infusion Pump , Sims Deltec, Inc., K982839

3. **Indications for Use (intended use)** The portable Crono infusion device has been designed for use in intravenous or subcutaneous infusion of medicines for pain management.

4. **Description of the Device**:. Microjet Crono PCA has been designed for the analgesic therapy with a flexible and precise drug's administration causing the minimum discomfort to the patient allowing to walking about. Microjet Crono PCA results to be, within its field, the most innovative instrument available in the market due to small dimension and easy-to-use. Outstanding technology degree has allowed to obtain high reliability degree for long time use without maintenance. A microprocessor runs the electronic circuitry allowing to program the flow seeing the duration of the infusion. A button allows the patient to administer an additional bolus as well seeing the infused volume when in process. The screen also allows to indicate the total of bolus that have been delivered within the infusion in course. A safety system is foreseen to unlock the keyboard to avoid unauthorized variation of the programmed parameters. In the event of occlusion of the catheter, Microjet Crono PCA allows to carry on the administration after the occlusion has been removed. This function is capable to highly reduce the risk of infusion not brought to end. Microjet Crono PCA is equipped with a liquid crystal display where the programmed data can be seen as well as the battery status.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, EMC, and user testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Characteristic	**Cadd-Legacy PCA Model 6300 Ambulatory Infusion Pump , Sims Deltec, Inc., K982839**	**Microjet *Crono* PCA ambulatory infusion pump**
Intended Use:	Designed for use in intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural, intrathecal infusion of medicines for pain management.	Intravenous or subcutaneous only.
Physical characteristics:		
Power Source	2 AA alkaline batteries, AC Adapter	Lithium battery (3V) of the 123 A type
Size	4.4 x 3.8 x 1.6 x in (112x 95x41 mm)	3" x 1.85" x 1.14" (77 x 47 x 29 mm)
Weight	13.8 oz (392 grams)	4.0 oz (115 g) (battery included).
Capacity	50 or 100 ml	10 or 20 ml
Warranty:	1 year	2 years

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of CANÈ S.r.l. that the Microjet Crono PCA is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 8 2002

Cane S. R. L.
C/O Mr. Daniel Kamm
Kamm & Associates
P. O. Box 7007
Deerfield, Illinois 60015

Re: K013822
Trade/Device Name: MicorJet Crono PCA
Regulation Number: 880.5725
Regulation Name: Infusion Pump, PCA
Regulatory Class: II
Product Code: MEA
Dated: February 11, 2002
Received: February 12, 2002

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K013822

Device Name: Microjet *Crono* PCA ambulatory infusion pump

Indications for Use: The **Microjet *Crono* PCA ambulatory infusion pump** device has been designed for use in intravenous or subcutaneous infusion of medicines for pain management.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013822